Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020 authorising the placing on the market of vitamin D2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1163

of 6 August 2020

authorising the placing on the market of vitamin D_2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001[(1)], and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470[(2)] establishing a Union list of authorised novel foods was adopted.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the update of the Union list.

(4) On 17 July 2018, the company Oakshire Naturals, LP. ('the applicant') submitted a request to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place vitamin D_2 mushroom powder on the Union market as a novel food. The application concerns the use of vitamin D_2 mushroom powder in a variety of foods and beverages for consumption by the general population, in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[(3)] excluding those intended for infants, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(4)], intended for individuals above 7 months of age.

(5) The applicant also introduced a request to the Commission for protection of proprietary data for scientific data submitted in support of the application, namely, the specifications for the raw materials and processing aids[(5)], the certificates of analysis and batch data of vitamin D_2 mushroom powder[(6)], and the vitamin D_2 mushroom powder stability reports[(7)].

(6) On 18 October 2018, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an assessment of vitamin D_2 mushroom powder as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 28 November 2019, the Authority adopted its scientific opinion 'Safety of vitamin D_2 mushroom powder as a novel food pursuant to Regulation (EU) 2015/2283'[(8)]. That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that vitamin D_2 mushroom powder is safe under the proposed uses and uses levels, when used in a variety of foods and beverages, in foods for special medical purposes excluding those intended for infants, and when used in food supplements intended for the general population above the age of 1 year. The Authority also noted, that in situations of high consumption of other foods containing or being fortified with vitamin D, the intake by infants of 7 to 12 months of food supplements containing the vitamin D_2 mushroom powder at levels equivalent to 10 μg of vitamin D, could result in combined overall intakes of vitamin D, which would exceed the Tolerable Upper Intake Levels ('UL') for vitamin D[(9)]. It is therefore appropriate to conclude that the intake of vitamin D from food supplements containing the vitamin D_2 mushroom powder at levels equivalent to 10 μg of vitamin D by infants 7 to 12 months of age, may not be in accordance with the conditions set out in Article 7 of Regulation (EU) 2015/2283 and such use should therefore not be authorised for this novel food.

(9) Therefore the scientific opinion gives sufficient grounds to establish that vitamin D_2 mushroom powder, under the proposed uses and uses levels, and when used in food supplements intended for the general population above the age of one year, complies with Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority considered that the data from the specifications for the raw materials and processing aids, the certificates of analysis and batch data of vitamin D_2 mushroom powder and the vitamin D_2 mushroom powder stability reports served as a basis to establish the safety of the novel food. On this basis the Commission considers that the conclusions on the safety of vitamin D_2 mushroom powder could not have been reached without the data from the report of these studies.

(11) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary data from Annex I (Raw materials and processing aids), Annex II (Certificates of Analysis and batch data) and Annex III (Stability reports) as regards vitamin D_2 mushroom powder, and to clarify their claim to an exclusive right of reference to these

reports and studies, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

(12) The applicant declared that, at the time the application was submitted, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use these studies.

(13) The Commission assessed all the information provided by the applicant and considered that the latter has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the data from these studies contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the applicant for a period of five years.

(14) However, restricting the authorisation of vitamin D_2 mushroom powder and of the reference to the scientific data contained in the applicant's file for the sole use of the applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on lawfully obtained information supporting the authorisation under this Regulation.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1 Vitamin D_2 mushroom powder as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established by Implementing Regulation (EU) 2017/2470.

2 For a period of five years from the date of entry into force of this Regulation only the applicant:

— Company: Oakshire Naturals, LP.

— Address: PO Box 388, Kennett Square, Pennsylvania 19348, United States

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of Oakshire Naturals, LP.

3 The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

The studies and reports contained in the applicant's file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283,

shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Oakshire Naturals, LP.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 August 2020.

For the Commission

The President

Ursula VON DER LEYEN